In the United States Court of Federal Claims

FOR PUBLICATION

No. 21-1728V
(Filed: August 14, 2024*)

STEPHANIE FELIX and ASHTON FELIX, *parents of E.A.F., a minor,*	)
Petitioners,	)
v.	)
SECRETARY OF HEALTH AND HUMAN SERVICES,	)
Respondent.	)

John L. Shipley, Davis, CA, for petitioners.

Mallori B. Openchowski, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, for respondent. With her on the briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, and *C. Salvatore D'Alessio*, Director, and *Heather L. Pearlman*, Deputy Director, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC.

OPINION AND ORDER

BONILLA, Judge.

Parents of a minor seek review of a decision of the United States Court of Federal Claims Office of Special Masters (OSM) denying entitlement under the National Childhood Vaccine Injury Act (Vaccine Act), 42 U.S.C. § 300aa-10 *et seq.* Petitioners specifically challenge OSM's dismissal of their Table Injury claim, attributed to their child's adverse effects to a Centers for Disease Control and

* This decision was initially filed under seal on July 30, 2024, in accordance with Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims, to allow the parties to propose redactions based upon privacy concerns. No proposed redactions were filed.

Prevention (CDC) recommended vaccination. OSM dismissed the petition relatively early in the proceedings "for failure to establish the statutory severity requirement." *Felix v. Sec'y of Health & Hum. Servs.*, No. 21-1728, 2024 WL 2831368 (Fed. Cl. Spec. Mstr. Apr. 29, 2024). For the reasons discussed herein, the Court finds OSM's decision was not arbitrary, capricious, an abuse of discretion, or otherwise contrary to law. Accordingly, the motion for review is DENIED and the OSM decision is SUSTAINED.

BACKGROUND

Petitioners Stephanie and Ashton Felix are the parents of an eight-year-old child identified herein as E.A.F. During a pediatric wellness visit on August 6, 2018, E.A.F. received the first dose of the measles, mumps, and rubella (MMR) vaccination. While the Felixes previously delayed certain CDC-recommended vaccines citing over-immunization concerns, the MMR vaccination was required for E.A.F. to attend preschool. Up until this point, E.A.F. was generally in good health and had no significant medical conditions.

Two weeks later, E.A.F. returned to the pediatrician after developing "bumps behind [his] head" and experiencing severe bruising. ECF 11-2 at 33–34. The pediatrician suspected immune thrombocytopenic purpura (ITP)[1] and instructed Ms. Felix to bring E.A.F. to the hospital for additional testing.[2] Upon admission, a complete blood count (CBC) revealed a low platelet count of 7,000/mm_3.[3] Confirming the ITP diagnosis, E.A.F. "responded well" to intravenous immune globulin (IVIG) treatment, increasing his platelet count to 20,000/mm_3 after only one dose.[4] ECF 8-2 at 14. The discharging physician directed that E.A.F. return in two days for another CBC. The doctor further recommended to "hold vaccines (except influenza vaccine) for at least 6 months after IVIG . . . [as E.A.F.] may not have full response to vaccines after recent IVIG administration." *Id.* The family was also advised to "avoid rough play." *Id.* at 15.

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[1] ITP is a blood disorder, characterized by low platelet levels, which can prevent blood from clotting and lead to severe bleeding and bruising. A typical platelet count is between 150,000 and 400,000 per cubic millimeter (mm_3), with a platelet count under 50,000/mm_3 indicating the patient is thrombocytopenic. 42 C.F.R. § 100.3(c)(7). ITP can also be distinguished between acute (short-term) ITP and chronic (long-term) ITP. Acute ITP is the most common type and often lasts less than six months. Chronic ITP lasts six months or longer and mostly affects adults with underlying health conditions. *See Nat'l Heart, Lung, and Blood Inst.*, Immune Thrombocytopenia, https://perma.cc/B559-XG58 ("Acute ITP in children often goes away on its own within a few weeks or months and does not return.") (last visited July 30, 2024).

[2] Given E.A.F.'s age and unexplained bumps and bruises, child protective services was notified.

[3] For clarity, the Court stylistically adopts the subscript cubic measurement (i.e., mm_3) to distinguish platelet counts from footnote numbers.

[4] Mild anemia (attributed to high milk intake) was also diagnosed, for which E.A.F. was prescribed iron supplements.

When E.A.F. returned to the hematology clinic on August 24, 2018, the CBC revealed a platelet count of 140,000/mm$_3$, noting however: "The reported platelet count may be inaccurate due to platelet clumping." *Id.* at 47. Three subsequent CBCs through October 18, 2018, measured platelet counts of between 72,000/mm$_3$ and 117,000/mm$_3$. *See* ECF 8-4 at 1–3. During a routine October 22, 2018 follow-up examination, a pediatric hematology-oncology fellow assessed E.A.F. as an otherwise healthy three-year-old "with ITP with overall stable platelet count and iron deficiency anemia that is improving on iron supplementation." ECF 8-2 at 52. The treatment plan included avoiding "live vaccines for 6–12 months after IVIG, and no rough play while thrombocytopenic." *Id.* at 56–57. CBCs administered on November 5, 2018, December 13, 2018, and April 1, 2019, measured E.A.F.'s platelet counts at 166,000/mm$_3$, 225,000/mm$_3$, and 301,000/mm$_3$, respectively. ECF 17-1 at 8–11.

E.A.F. went to his primary care physician for a regular checkup on October 14, 2019. During this wellness visit, E.A.F. was assessed as a "healthy" four-year-old "with normal growth and developmental milestones." ECF 11-2 at 48. E.A.F. was nonetheless medically exempted from receiving the second (and final) dose of the MMR vaccine due to his previous adverse reaction. Since then, E.A.F.'s medical records reflect he was otherwise up to date on vaccinations and that his platelet counts never fell below 270,000/mm$_3$–characterized as "completely normal." *Id.* at 58, 64; ECF 8-2 at 59–60.

The Felixes filed a petition for compensation under the National Vaccine Injury Compensation Program's Vaccine Injury Table on August 19, 2021. Finding that the claim failed to demonstrate the Vaccine Act's six-month residual effect severity requirement, OSM granted respondent's motion to dismiss on April 29, 2024. In support, OSM explained that E.A.F.'s ITP likely resolved within three months, evidenced by his platelet count returning to normal levels. OSM further explained that, under the recent decision of the United States Court of Appeals for the Federal Circuit in *Wright v. Secretary of Health & Human Services*, 22 F.4th 999 (Fed. Cir. 2022), petitioners' reliance on continued testing, restrictions on physical activity, and delayed vaccines was misplaced. Petitioners timely filed this motion for review.

DISCUSSION

I. Standard of Review

In reviewing a Vaccine Act decision, this Court may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or

> otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
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> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The Federal Circuit clarified the applicable standards of review as follows: findings of fact are reviewed for arbitrariness or capriciousness; discretionary rulings are reviewed for abuse of discretion; and legal conclusions are reviewed *de novo*. *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001) (citations omitted).

II. OSM Dismissal

The motion for review asserts four bases to set aside OSM's decision and remand this matter for continued proceedings. First, petitioners claim OSM applied the wrong legal standard in granting respondent's motion to dismiss. Second, petitioners allege OSM erred in precluding their retention and presentation of an expert witness. Third and fourth, petitioners assert OSM erroneously concluded that delayed vaccines and restrictions of physical activity, respectively, did not qualify as residual effects of E.A.F.'s ITP diagnosis. These intertwined issues are resolved below.

Addressing the proper standard of review, petitioners aver respondent's motion to dismiss was more akin to a motion for summary judgment and, thus, OSM should have converted the dispositive motion and drawn all inferences in their favor as the non-movant. In support, petitioners cite Vaccine Rule 8(d), which states: "The special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply." The Vaccine Rules, sanctioned by the Federal Circuit, belie this argument. Nevertheless, whether decided as a motion to dismiss or a motion for summary judgment, the Felixes were entitled to receive–and did receive–all reasonable inferences drawn in their favor as the non-movant.

Vaccine Rule 8(a) allows special masters to "determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties." This rule was meant to "provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions." *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1364 (Fed. Cir. 2020) (quoting 42 U.S.C. § 300aa-12(d)(2)(A)). Contrary to petitioners' contention, subsection (d) twice employs the permissive term "may" to describe the discretionary decision whether to conduct an evidentiary hearing and, critical here, identify the non-exhaustive types of alternative proceedings OSM may conduct. A plain reading

of the text allows for–but does not expressly limit non-evidentiary hearing proceedings to–motions for summary judgment. *Id.* at 1366 ("Rule 8(d) contemplates that special masters can decide cases on written submissions *other* than motions for summary judgment.") (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012)).[5] Indeed, the Federal Circuit recently concluded that special masters are authorized to entertain motions to dismiss for failure to state a claim upon which relief can be granted under the guise of Rule 12(b)(6). *W.J. v. Sec'y of Health & Hum. Servs.*, 93 F.4th 1228, 1242–43 (Fed. Cir. 2024).

Even so, special masters do not enjoy unlimited discretion to resolve disputes at any point in the litigation:

> The Vaccine Act requires special masters to determine whether hearings or witness testimony are reasonable and necessary. 42 U.S.C. § 300aa-12(d)(3)(B). Special masters must "afford[] each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision." Vaccine Rule 3(b)(2). As a result, special masters must determine that the record is comprehensive and fully developed before ruling on the record. *Simanski*, 671 F.3d at 1385 (finding due process violation where special master ruled on the record at "an early procedural stage" before respondent had "present[ed] its position with respect to the petition and the supporting evidence"); *Jay v. Sec'y of Dep't of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993).

Kreizenbeck, 945 F.3d at 1366. To this end, as made plain in *Jay*, the procedural posture of the dispositive motion considered by OSM carries with it the standard of review generally commensurate with that motion:

> Thus, as our previous discussion makes clear, in vaccine cases, as in other cases, summary judgment is summary judgment. If to dispose of the case the special master must resolve conflicts of fact or weigh conflicting evidence, or is statutorily constrained to do so, he or she may not render summary judgment. We will therefore treat this appeal as any other involving a grant of summary judgment, determining *de novo* whether there exist genuine issues of material fact and whether one of the parties is entitled to judgment as a matter of law.

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[5] *Compare, e.g.*, *Swint-Moore v. Sec'y of Health & Hum. Servs.*, No. 18-1112, 2022 WL 1124478, at *6 (Fed. Cl. Spec. Mstr. Mar. 29, 2022) ("Although [r]espondent styled his motion as a motion to dismiss, I am construing it as a motion for summary judgment."), *with Michie v. Sec'y of Health & Hum. Servs.*, No. 19-453, 2023 WL 10410004 (Fed. Cl. Spec. Mstr. Dec. 4, 2023) (OSM granted motion to dismiss MMR-based ITP claim for failure to satisfy Vaccine Act's six-month residual effect severity requirement).

998 F.2d at 983. The same holds true in resolving motions to dismiss. *See, e.g.*, *W.J.*, 93 F.4th at 1235. Thus, in ruling upon a motion to dismiss, the special master must accept as true the facts asserted by the petitioner in determining whether the claim for relief under the Vaccine Act is both "sufficient" and "plausible on its face." *Id.* (citing cases).

The record presented demonstrates OSM satisfied the foregoing procedural and substantive requirements in this case. Procedurally, OSM afforded the Felixes ample opportunity to present their claim and address the noticed challenge (i.e., Vaccine Act's six-month residual effect severity requirement), including filing extensive medical records, an amended petition, and a series of briefs and affidavits in response to the motion to dismiss.[6] As for the Felixes' asserted request to retain and present expert testimony, the undersigned concludes OSM did not abuse its discretion in this regard. Not all vaccine cases merit expert witness testimony particularly where, as here, petitioners have been given "a full and fair opportunity to present [their] case and creat[e] a record sufficient to allow review of the special master's decision" through medical evidence and proffered affidavits in accordance with Vaccine Rule 3(b)(2). *See, e.g.*, *K.A. v. Sec'y of Health & Hum. Servs.*, 164 Fed. Cl. 98, 115–19 (2022) (OSM's decision to deny requests to retain and present particular expert witness did not deprive the parties of "a full and fair opportunity to present his case" or otherwise amount to an abuse of discretion), *aff'd*, No. 23-1315, 2024 WL 2012526 (Fed. Cir. May 7, 2024) (per curiam) (table); *Guilliams v. Sec'y of Dep't of Health & Hum. Servs.*, No. 11-716, 2012 WL 1145003, at *10 n.20 (Fed. Cl. Mar. 14, 2012) ("An expert opinion may not be required for claims that present a well-established history of recovery under the [Vaccine] Program or that are listed on the Vaccine Injury Table.") (citations omitted).

Here, more specifically, there is a notable disconnect between the expert witness request made during the OSM proceedings and the resulting harm asserted now. In opposing the motion to dismiss–and buried in a footnote–petitioners proffer: "If necessary, [p]etitioners are confident that they will be able to present an expert opinion from a child psychiatrist/psychologist who can speak to the psychological effect that E.A.F.'s ITP injury had on him, and the duration of such [an] effect." ECF 30 at 11 n.3. Petitioners thereafter include two generic references to allowing them "the opportunity to establish through evidence and expert opinion that E.A.F.'s residual effects and complications from the ITP injury he suffered following his MMR vaccination lasted more than six months." *Id.* at 10; *accord id.* at 8. In their motion for review, petitioners shift their focus away from the alleged psychological impact and instead assert that an expert witness could have substantiated their claims of:

[6] *See, e.g.*, ECF 8, 11, 17 (medical records), 18 (amended petition), 24 (scheduling order noticing challenge), 26–27 (respondent's report, motion to dismiss), 29-1 (petitioners' affidavit), 30 (response to motion to dismiss), 33 (scheduling order noting concerns with establishing severity requirement and allowing submission of additional support), 36–38 (petitioners' affidavits, supplemental brief), 40 (respondent's supplemental brief), 41 (petitioners' supplemental brief).

(1) "ongoing complications associated with ITP and the treatment necessary to address these complications," (2) "the reasonableness, and medical necessity, for E.A.F. adhering to restrictions on physical activity," and (3) "the reasonableness, and medical necessity, for E.A.F. to avoid receiving certain vaccinations."[7] ECF 43-1 at 16. Even putting aside the substantive shift from psychological to physiological manifestations, the Federal Circuit's recent decision in *Wright* underscores the implausibility that an expert witness could overcome the statutory deficiency in petitioners' vaccine claim. Accordingly, there is no reason for this Court to set aside OSM's discretionary decision to preclude the retention and presentation of expert witness testimony on these issues.

In *Wright*, the Federal Circuit considered a factual scenario strikingly similar to the one presented today: a two-year-old child otherwise in good health experienced ITP roughly two weeks after receiving the MMR vaccine. 22 F.4th at 1003. When admitted to the hospital, the child exhibited severe bruising and a low platelet count (i.e., below 50,000/mm_3). *Id.* Within three months, the child's platelet count returned to (and thereafter maintained) normal levels. *Id.* Seeking to satisfy the six-month residual effect severity requirement under 42 U.S.C. § 300aa-11(c)(1)(D) notwithstanding the acute nature of the diagnosed blood disorder, the petitioner in *Wright* cited the child's incidents of bruising and consequent blood tests to rule out ITP over the next two years. 22 F.4th at 1003–04. Rejecting both bases, the Federal Circuit succinctly explained: "A residual effect must be a change within the patient that is caused by the vaccine injury." *Id.* at 1001; *accord id.* at 1004–05.

The Federal Circuit noted that in a typical ITP case the blood disorder "is rarely chronic, i.e., lasting more than 6 months, and chronic cases are thought to be the result of an autoimmune disorder rather than viral vaccination or viral infection." *Id.* at 1003 (citing National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table–II, 60 Fed. Reg. 56,289, 56,295 (Nov. 8, 1995)). Like E.A.F, the child in *Wright* experienced a significant platelet level drop after an MMR vaccine and recovered within three months. To ensure their continued good health and promptly diagnose any recurrence, both children underwent periodic CBCs to monitor platelet levels. The Federal Circuit squarely held that such ongoing monitoring does not satisfy the Vaccine Act's six-month residual effect severity requirement.[8] *Id.* at 1005–07.

In E.A.F.'s case, the proactive protective measures also included restricting physical activity and delaying scheduled vaccinations for specified periods of time. Contrary to petitioners' argument, the recommended precautions are not an extended

[7] Petitioners' motion for review includes only one mention of "E.A.F.'s psychological well-being" in the statement of facts section of the brief. *See* ECF 43-1 at 7.

[8] The episodic bruising, in turn, was similarly not attributable to ITP once the acute blood disorder resolved. *Id.* at 1005.

course of treatment (or ongoing medical care) contemplated by–and potentially exempted from–the holding in *Wright*. As explained by the Federal Circuit: "During a long course of treatment, the patient generally has some lingering condition such that symptoms will likely recur if the treatment were stopped. Otherwise, the long course of treatment would not be necessary." *Id.* at 1007. The recommended restriction on E.A.F.'s physical activity was "no rough play *while thrombocytopenic*." ECF 8-2 at 56–57 (emphasis added). E.A.F.'s platelet count returned to normal levels as of November 5, 2018 (i.e., within three months of the vaccine) and, thereafter, continuously measured above 150,000/mm$_3$. Put simply, the acute blood disorder did not linger beyond the critical six-month mark, and there were no recurring attributable symptoms.[9]

Similarly, the recommendation that E.A.F. "should not have any live vaccines for 6–12 months *after IVIG*," *id.* (emphasis added), was not attributed to the possible recurrence or exacerbation of ITP. Rather, it was to ensure the efficacy of future vaccines which might be compromised by the infusion of pooled antibodies and biological agents administered through the August 2018 IVIG treatment. The facts presented in this case simply do not lend themselves to a finding that the doctor's orders qualify as: (1) long-lasting residual effects of acute ITP, (2) a likelihood of recurrence absent proactive (and invasive) medical treatment, or (3) some somatic change underlying an undiagnosed chronic blood disorder or related condition.[10]

The undersigned finally circles back to OSM's substantive consideration of the respondent's motion to dismiss, and specifically, the lens through which OSM viewed the Felixes' claim and record evidence. As detailed herein, there is no basis to conclude OSM "has failed to consider the relevant evidence of record, drawn implausible inferences, or failed to provide a rational basis for the decision." *See W.J.*, 93 F.4th at 1235. Adhering to the precedent and teachings of the Federal Circuit's recent decision in *Wright*, OSM properly concluded that the Felixes' claim of MMR-induced acute ITP–as pled and substantiated–failed to satisfy the Vaccine Act's six-month residual effect severity requirement. To conclude otherwise would require

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[9] The temporary limitation placed on E.A.F.'s physical activity, while understandably difficult for him and his family given his age and relative cognitive ability, also did not rise to qualifying painful suffering contemplated under *Wright*. *See* 22 F.4th at 1006–07.

[10] In *Leming v. Secretary of Health & Human Services*, OSM categorically held that a delayed vaccine due to an increased related health risk does not satisfy the Vaccine Act's six-month residual effect severity requirement. *See* No. 18-232, 2022 WL 3371016, at *8 (Fed. Cl. Spec. Mstr. Jan. 26, 2022) ("[T]he mere risk of a future associated problem that could be triggered a second time by vaccination cannot satisfy severity.") (citing cases), *reconsideration denied*, 2022 WL 3444742 (Fed. Cl. Spec. Mstr. Feb. 18, 2022), *motion for review denied*, 161 Fed. Cl. 744 (2022), *rev'd on other grounds*, 98 F.4th 1107 (Fed. Cir. 2024). In deciding the motion for review and appeal in *Leming*, respectively, neither this Court nor the Federal Circuit found it necessary to address the issue. *See* 161 Fed. Cl. at 760 n.6; 98 F.4th at 1113 n.3. Likewise, the undersigned limits today's decision to the conclusion that delayed vaccinations attributed to an IVIG treatment administered to resolve acute ITP cannot singularly satisfy the statutory residual effect severity requirement.

assuming facts belied by the record presented–i.e., recurring or chronic ITP despite temporal lab results documenting E.A.F.'s platelet count returned to (and thereafter maintained) normal levels within three months of the MMR vaccine. OSM thoughtfully examined this evidence in reaching its decision, considering the record in the light most favorable to the Felixes. As such, there is no basis to find the OSM decision "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B).

CONCLUSION

For the foregoing reasons, petitioners' motion for review (ECF 43) is DENIED and the OSM decision (ECF 42) is SUSTAINED. The Clerk of Court is directed to ENTER judgment accordingly.

It is so **ORDERED**.

Armando O. Bonilla
Judge